IFW

Docket No.: V9661.0074
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Hsiang-Fu Kung et al.

Confirmation No.: NYA

Application No.: 10/801,648

Group Art Unit: N/A

Filed: March 17, 2004

Examiner: Not Yet Assigned

For: A COMBINED ADENO-ASSOCIATED VIRUS AND ADENOVIRUS COCKTAIL GENE DELIVERY SYSTEM FOR HIGH EFFICIENCY GENE EXPRESSION WITHOUT ELICITING IMMUNE RESPONSE IN IMMUNO-COMPETENT SUBJECTS

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Timing of Filing of the Information Disclosure Statement:

☒ This IDS is being filed before the First Office Action[1].

[1] The IDS should, where possible, include a certification under 37 C.F.R. §1.97(e).

☐ This IDS is being filed after the issuance of the First Office Action but before the issuance of a Final Office Action[2].

☐ This IDS is being filed after the issuance of a Final Office Action but before the payment of the Final Fee[3].

Certifications:

If checked, the undersigned makes the following statement(s):

☐ Statement under 37 CFR § 1.97(e):

Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement; or

No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

☐ Statement Under 37 C.F.R. § 1.704(d):

Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application less than thirty days prior to the filing of this information disclosure statement.

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[2] The IDS *must* include *either* a certification under 37 C.F.R. §1.97(e) *or* the fee set forth in 37 C.F.R. §1.17(p).

Fee Required by 37 C.F.R. § 1.97(c)(2) or 1.97(d)(2):

☐ If checked, the fee of $180.00 set forth in 37 C.F.R. §1.17(p) is attached.

Copies of Information:

In accordance with 37 C.F.R. §1.98(a), the following are enclosed:

☒ A legible copy[4] of each document (or relevant portion thereof) is cited in the attached PTO/SB/08.

☐ With respect to any information which is not in English, a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, is attached. This concise explanation is provided by way of:

☐ A translation of the relevant portions of the non-English language information[5];

☐ A statement explaining the relevant portions of the non-English language information;

☐ A copy [and, where not in the English language, a translation] of at least the relevant portion(s)[6] of the communication from a foreign patent

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[3] The IDS *must* include *both* a certification under 37 C.F.R. §1.97(e) *and* the fee set forth in 37 C.F.R. §1.17(p).

[4] A legible copy of the document is not required if (1) the information was previously cited by, or submitted to, the Office and considered by the Office in a prior U.S. application to which this application claims priority, provided that the prior application is properly identified in this IDS, and (2) the IDS submitted in the earlier application complies with 37 C.F.R. § 1.98(a) – (c). This exception does not apply to information cited in an International Application.

[5] 37 C.F.R. §1.98(a)(3)(ii) *requires* that an English language translation be provided when a translation of the document, or portion thereof, "is within the possession, custody or control of, or is readily available to any individual designated in 37 C.F.R. § 1.56(c)."

office in a counterpart foreign application in which the information was cited; or

☐ This information is contained in the specification of the present application.

☐ In accordance with 37 C.F.R. 1.98(d), copies of the cited documents are not enclosed as they were provided in application Serial No. , filed , which the present application relies upon for an earlier effective filing date under 35 U.S.C. 120.

Materiality:

Whether or not the information and references disclosed in this Information Disclosure Statement is "material" pursuant to 37 CFR 1.56, this submission is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists.

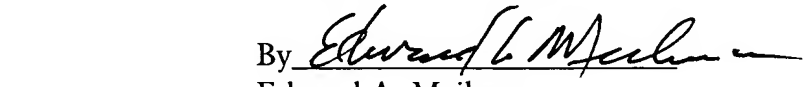
It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

[6] The relevant portion is that portion which indicates the degree of relevance found by the foreign patent office. This may be an explanation of which portion of the of the reference is particularly relevant, to which

In the event the actual fee is inadvertently not enclosed or if any additional fee during the prosecution of this application is not paid, the Patent Office is authorized to charge the underpayment to Deposit Account No. 50-2215.

Dated: July 15, 2004

Respectfully submitted,

By 

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claims it applies, or merely an "X", "Y", or "A" indication on a search report. MPEP §609 III A(3).

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known	
Application Number	10/801,648-Conf. #2232
Filing Date	March 17, 2004
First Named Inventor	Hsiang-Fu Kung
Art Unit	N/A
Examiner Name	Not Yet Assigned
Attorney Docket Number	V9661.0074

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA**	US-5,436,146.	07-25-1995	THOMAS E. SHENK	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	BA	WO 94/12649	06-09-1994	Richard J. Gregory et al.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (**) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	CA	MONAHAN ET AL., "Adeno-associated virus vectors for gene therapy: more pros than cons?, 2000, Mol. Med. Today 6:433-440.	
	CB	FLOTTE AND CARTER, "Adeno-associated virus vector for gene therapy,"1995, Gene Ther. 2:357-362.	
	CC	RABINOWITZ ET AL., "Adeno-associated virus expression systems for gene transfer," 1998, Curr. Opin. Biotechnol., 9:470-475.	
	CD	MUZYCZKA, "Current Topics in Microbiology and Immunology," 1992, Curr. Top. Microbiol. Immunol., 158:97-129.	
	CE	SAMULSKI ET AL., "Helper-Free Stocks of Recombinant Adeno-Associated Viruses: Normal Integration Does Not Require Viral Gene Expression," 1989, Virol. 63:3822-3828.	
	CF	XIAO ET AL., "Efficient Long-Term Gene Transfer into Muscle Tissue of Immunocompetent Mice by Adeno-Associated Virus Vector," 1996, J. Virol. 70:8098-8108.	
	CG	WOZNEY AND ROSEN, "Bone Morphogenetic Protein and Bone Morphogenetic Protein Gene Family in Bone Formation and Repair," 1998, Clin. Orthop. 346:26-37.	
	CH	SAKOU, "Bone Morphogenetic Proteins: From Basic Studies to Clinical Approaches," 1998, Bone 22:591-603.	
	CI	CHEN, "Orthopedic applications of gene therapy," 2001, J. Orthop. Sci. 6:199-207.	
	CJ	SANDHU ET AL., "Effect of Interleukin-6 Secreted by Engineered Human Stromal Cells on Osteoclasts in Human Bone," 1999, Bone 24:217-227.	
	CK	FANG ET AL., "Stimulation of new bone formation by direct transfer of osteogenic plasmid genes," 1996, Proc. Natl. Acad. Sci. 93:5753-5758.	
	CL	BONADIO ET AL., "Localized, direct plasmid gene delivery in vivo: prolonged therapy results in reproducible tissue renegeneration", 1999, Nat. Med. 5:753-759.	
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	CN	LIEBERMAN ET AL., "The Effect of Regional Gene Therapy with Bone Morphogenetic	

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Sheet 2 of 3

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Filing Date	March 17, 2004
First Named Inventor	Hsiang-Fu Kung
Art Unit	N/A
Examiner Name	Not Yet Assigned
Attorney Docket Number	V9661.0074

		Protein-2-Producing Bone-Marrow Cells on the Repair of Segmental Femoral Defects in Rats," 1999, J. Bone. Joint. Surg. 81A:905-917.	
	CO	CHEN ET AL., "In vivo new bone formation by direct transfer of adenoviral-mediated bone morphogenetic protein-4 gene," 2002, Biochem. Biophys. Res. Commun. 98:121-127.	
	CP	BREITBART ET AL., "Gene-Enhanced Tissue Engineering: Applications for Bone Healing Using Cultured Periosteal Cells Transduced Retrovirally with the BMP-7 Gene," 1999, Ann. Plast. Surg. 42:488-495.	
	CQ	PENG ET AL., "Development of an MFG-Based Retroviral Vector System for Secretion of High Levels of Functionally Active Human BMP4," 2001, Mol. Ther. 4:95-104.	
	CR	PONNAZHAGAN S ET AL., "Adeno-associated Virus for Cancer Gene Therapy," 2001, Cancer Res. 61:6313-6321.	
	CS	LAI CC ET Al., 2001, "Suppression of Choroidal Neovascularization by Adeno-associated Virus Vector Expressing Angiostatin," Invest. Ophthalmol. Vis. Sci. 42(10):2401-7.	
	CT	NGUYEN JT ET AL., "Adeno-associated Virus-mediated Delivery of Antiangiogenic Factor as an Antitumor Strategy," 1998, Cancer Research 58:5673-7.	
	CU	RENGACHARY ET AL., "Bone healing and spinal fusion," 2002, Neurosurg Focus 13 (6):1-6.	
	CV	KOZARSKY AND WILSON, "Gene therapy: adenovirus vectors," 1993, Current Opinion in Genetics and Development 3:499-503 present a review of adenovirus-based gene therapy.	
	CW	BOUT ET AL., "Lung Gene Therapy: In Vivo Adenovirus-Mediated Gene Transfer to Rhesus Monkey Airway Epithelium," 1994, Human Gene Therapy 5:3-10.	
	CX	ROSENFELD ET AL., "Adenovirus-Mediated Transfer of a Recombinant a1-Antitrypsin Gene to the Lung Epithelium in Vivo," 1991, Science 252:431-434.	
	CY	ROSENFELD ET AL., "In Vivo Transfer of the Human Cystic Fibrosis Transmembrane Conductance Regulator Gene to the Airway Epithelium," 1992, Cell 68:143-155.	
	CZ	MASTRANGELI ET AL., "Diversity of Airway Epithelial Cell Targets for In Vivo Recombinant Adenovirus-mediated Gene Transfer," 1993, J. Clin. Invest. 91:225-234.	
	CA1	WANG, ET AL., "A packaging cell line for propagation of recombinant adenovirus vectors containing two lethal gene-region deletions,'1995, Gene Therapy 2:775-783.	
	CB1	WALSH ET AL., "Gene Therapy for Human Hemoglobinopathies," 1993, Proc. Soc. Exp. Biol. Med. 204:289-300.	
	CC1	**XU, RA ET AL., 2001, "Perarolly transduction of diffuse cells and hepatocyte insulin leading to euglycemia in diabetic rats, Mol Ther 3:S180.*****	
	CD1	DURING MJ ET AL., "Paroral gene therapy of lactose intolerance using an adeno-associated virus vector, " 1998, Nature Med. 4:1131- 1135.	
	CE1	DURING MJ ET AL., "An oral vaccine against NMDAR1 with efficacy in experimental stroke and epilepsy, 2000, Science 287:1453-1460.	
	CF1	GRIMM ET AL., "Novel Tools for Production and Purification of Recombinant Adenoassociated Virus Vectors," 1998, Hum Gene Ther 9:2745-2760.	
	CG1	KLEIN ET AL., "High-velocity Microprojectiles for Delivering Nucleic Acids Into Living Cells," 1992, Biotechnology 24:384-386.	
	CH1	GOOMER ET AL., "High-efficiency non-viral transfection of primary chondrocytes and perichondrial cells for ex-vivo gene therapy to repair articular cartilage defects," 2001, Osteoarthritis Cartilage 9:249-256	
	CI1	BONADIO ET AL., "Localized, direct plasmid gene delivery in vivo: prolonged therapy results in reproducible tissue regeneration," 1999, Nat Med 5:753-759.	
	CJ1	EVANS ET AL., "Clinical Trial to Assess the Safety, Feasibility, and Efficacy of Transferring a Potentially Anti-Arthritic Cytokine Gene to Human Joints with Rheumatoid Arthritis," 1996, Hum Gene Ther 7:1261-1280.	
	CK1	ENGSTRAND ET AL., "Transient Production of Bone Morphogenetic Proteinc 2 by Allogeneic Transplanted Transduced Cells Induces Bone Formation," 2000, Hum Gene Ther 11:205-211.	
	CL1	BREITBART ET AL., "Gene-Enhanced Tissue Engineering: Applications for Bone Healing	

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Attorney Docket Number	V9661.0074

		Using Cultured Periosteal Cells Transduced Retrovirally with the BMP-7 Gene," 1999, Ann Plast Surg 42:488-495.	
	CM1	ALDEN ET AL., "In Vivo Endochondral Bone Formation Using a Bone Morphogenetic Protein 2 Adenoviral Vector," 1999, Hum Gene Ther 10:2245-2253.	
	CN1	VARADY ET AL., "Morphologic Analysis of BMP-9 Gene Therapy-Induced Osteogenesis," 2001, Hum Gene Ther 12:697-710.	
	CO1	LIEBERMAN ET AL., "The Effect of Regional Gene Therapy with Bone Morphogenetic Protein-2-Producing Bone-Marrow Cells on the Repair of Segmental Femoral Defects in Rats," 1999, J Bone Joint Surg 81A:905-917.	
	CP1	FRANCESCHI ET AL., "Gene Therapy for Bone Formation: In Vitro and In Vivo Osteogenic Activity of an Adenovirus Expressing BMP7"," 2000, J Cell Chem 78:476-486.	
	CQ1	JIANG ET AL., "Local High-Capacity Adenovirus-Mediated mCTLA4Ig and mCD40lg Expression Prolongs Recombinant Gene Expression in Skeletal Muscle," 2001, Mol Ther 3:892-900.	
	CR1	KATAGIRI ET AL., "Bone Morphogenetic Protein-2 Converts the Differentiation Pathway of C2C12 Myoblasts into the Osteoblast Lineage," 1994, J Cell Biol 127:1755-1766.	
	CS1	WOZNEY ET AL., "Bone Morphogenetic Proteins: From Basic Studies to Clinical Approaches," 1998, Bone 22:591-603.	
	CT1	BLAU ET AL., "Molecular Medicine Muscle-Mediated Gene Therapy," 1995, N Engl J Med 333:1554-1556.	
	CU1	YURCHENCO ET AL., "Assembly of Basement Membranes," 1990, Ann N Y Acad Sci 580:195-213.	
	CV1	PRUCHNIC ET AL., "The Use of Adeno-Associated Virus to Circumvent the Maturation-Dependent Viral Transduction of Muscle Fibers," 2000, Hum Gene Ther 11:521-536.	
	CW1	NALBANTOGLU ET AL., "Expression of the Primary Coxsackie and Adenovirus Receptor Is Downregulated during Skeletal Muscle Maturation and Limits the Efficacy of Adenovirus-Mediated Gene Delivery to Muscle Cells," 1999, Hum Gene ther 10: 1009-1019.	
	CX1	SNYDER ET AL., "Efficient and Stable Adeno-Associated Virus-Mediated Transduction in the Skeletal Muscle of Adult Immunocompetent Mice," 1997, Hum Gene Ther 8:1891-1900.	
	CY1	REDDI ET AL., "Cell Biology and Biochemistry of Endochondral Bone Development," 1981, Coll Relat Res 1:209-226.	
	CZ1	LEE ET AL., "Clonal Isolation of Muscle-derived Cells Capable of Enhancing Muscle Regeneration and Bone Healing," 2000, J Cell Biol 150:1085-1099.	
	CA2	APPARAILLY ET AL., "Tetracycline-Inducible Interleukin-10 Gene Transfer Mediated by an Adeno-Associate Virus: Application to Experimental Arthritis," 2002, Hum Gene Ther 13:1179-1188.	
	CB2	YAKOBSON ET Al., "Replication of Adeno-Associated Virus in Cells Irradiated with UV Llight at 254 nm," 1989, J. Virol. 63:1023-1030.	
	CC2	YAKOBSON ET AL., "Replication of Adeno-Associated Virus in Synchronized Cells without the Addition of a Helper Virus," 1987, J. Virol. 61:972-981.	
	CD2	FERRARI ET Al., "Second-Strand Synthesis Is a Rate-Limiting Step for Efficient Transduction by Recombinant Adeno-Associated Virus Vectors," 1996, J. Virol. 70:3227-3234.	
	CE2	FISHER ET AL., "Transduction with Recombinant Adeno-Associated Virus for Gene Therapy Is Limited by Leading-Strand Synthesis," 1996, J. Virol. 70:520-532.	
	CF2	OKUBO ET AL., "Osteoinduction by Bone Morphogenetic Protein-2 via Adenoviral Vector under Transient Immunosuppression," 2000, Biochem. Biophys. Res. Commun. 267:382-387.	

*****Listed but not enclosed. Will forward upon receipt.**

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.